

From: Norman, Caffey
To: [Holloman, Vincia](#); [Dunkin, Ann](#); [Moser, Rebecca](#); [Kirby, Kevin](#)
Cc: [Wheeler, Cindy](#); fgraul@hsia.org; [Morris, Jeff](#)
Subject: RE: Request for Reconsideration of EPA's Response to RFC #16001
Date: Wednesday, April 19, 2017 12:55:01 PM
Attachments: [removed.txt](#)
[Halogenated Solvents Industry Alliance TCE-MC-NMP EOCP 2017-04-18.pdf](#)

Hi Kevin and Vincia, to follow up on conversation just now I attach the letter from OCSPP to HSIA granting a 30-day extension for comments on EPA's proposed ban on TCE in vapor degreasing (82 Fed. Reg. 7432, as extended at 82 Fed. Reg. 10732 (Feb. 15, 2017)) to May 19, 2017. We simply want to make the deadline to submit a Request for Reconsideration of EPA's denial of HSIA's RfC of the TCE TSCA Work Plan Assessment coextensive with the new comment deadline for the proposed ban, which is based on that Work Plan Assessment. Thank you for your willingness to reach out to Jeff Morris to coordinate on this.

Best,



W. Caffey Norman

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From: Norman, Caffey
Sent: Friday, April 07, 2017 5:05 PM
To: 'Holloman, Vincia'; Dunkin, Ann; Moser, Rebecca; Kirby, Kevin
Cc: Wheeler, Cindy; Faye Graul (fgraul@hsia.org)
Subject: RE: Request for Reconsideration of EPA's Response to RFC #16001

Dear Ms. Holloman,

Thank you so much for your response to our request for an extension to submit a Request for Reconsideration of EPA's denial of HSIA's Request for Correction (RFC) of the TCE TSCA Work Plan Assessment. Regrettably, circumstances beyond our control compel us to seek a further extension beyond April 20, 2017. We made the extension request on the basis that results would be available by February 2017 from a study HSIA sponsored at Charles River Laboratories to try to replicate the cardiovascular effects seen by Johnson *et al.* (2003), which is the toxicological value driving the conclusions of the TCE Work Plan Assessment. (For both acute and chronic (non-cancer) risks, EPA determined that "the greatest risk is for developmental effects (*i.e.*, fetal cardiac defects)" as derived using Johnson *et al.* (2003). See 82 Fed. Reg. 7432, 7438-39 (Jan. 19, 2017).)

The Charles River study was intended specifically to try to replicate the cardiovascular effects seen by Johnson *et al.* (2003), which no laboratory to date has been able to reproduce, in an EPA Guideline study that meets Good Laboratory Practices. The Protocol was signed on October 6, 2016 and the in-life portion of the study was conducted during October and November 2016.

Unfortunately, we were recently notified by the laboratory that the concentrations of TCE measured in the drinking water solutions were found to be below the acceptable target range of 100% \pm 10%, invalidating the study. The laboratory has conducted additional studies to identify the source of the deviation and the study will be rerun as soon as dosing methodological issues are resolved and scheduling permits, with a target of having results available by August 2017. As opposed to EPA's proposed reliance on the so far unreproducible Johnson *et al.* study, the results of this study will

provide a record for EPA decision-making consistent with the requirements of TSCA § 26(h) that § 6 rulemaking be based on the “best available science.”

Accordingly, we respectfully request that the deadline to submit a Request for Reconsideration of EPA’s denial of HSIA’s RFC of the TCE TSCA Work Plan Assessment be extended to August 17, 2017. We are copying Cindy Wheeler on this correspondence, so that our request can be considered in connection with a request we submitted on March 17 to extend the comment deadline on EPA’s proposed ban on TCE in vapor degreasing, 82 Fed. Reg. 7432, as extended at 82 Fed. Reg. 10732 (Feb. 15, 2017). These comments are due April 19, 2017, and we similarly requested that the deadline be extended by 120 days to August 17, 2017.

Please do not hesitate to contact me if you need more information as you consider this request.

Thanks,



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From: Holloman, Vincia [<mailto:Holloman.Vincia@epa.gov>]

Sent: Tuesday, January 10, 2017 6:42 PM

To: Norman, Caffey; Jones, Jim; fgraul@hsia.org

Cc: Dunkin, Ann; Moser, Rebecca; Kirby, Kevin; Holloman, Vincia

Subject: Request for Reconsideration of EPA's Response to RFC #16001

Mr. Norman:

I am granting your request for an extension to submit a Request for Reconsideration (RFR) to HSIA’s Request for Correction (RFC), concerning TCE and the TSCA workplan. Pursuant to the “*EPA Information Quality Guidelines*” you have 90 days within the date of response to the RFC to submit the RFR. The response to your RFC, #16001 was issued on November 4, 2016 . The deadline for submitting an RFR is March 20, 2017. We have taken into consideration the delay in your receipt of our response on November 30, 2016 and are extending the deadline to April 20, 2017. Upon receipt, your RFR will undergo transparent and uncompromised review in accordance with the EPA IQG process.

Please accept my apology for any inconvenience our previous communications may have caused you and your associates, and do not hesitate to contact me or my staff for assistance with future IQG-related issues. I can be reached on 202 564 5176 or via email at Holloman.vincia@epa.gov.

Sincerely,

Vincia Holloman

Acting Director

Enterprise Quality Management Division

From: Norman, Caffey [<mailto:caffey.norman@squirepb.com>]

Sent: Wednesday, January 04, 2017 12:52 PM

To: Holloman, Vincia <Holloman.Vincia@epa.gov>; Dunkin, Ann <Dunkin.Ann@epa.gov>; Jones, Jim <Jones.Jim@epa.gov>

Cc: Jones, Monica <Jones.Monica@epa.gov>; Kirby, Kevin <KIRBY.KEVIN@EPA.GOV>; fgraul@hsia.org; Quality <Quality@epa.gov>

Subject: RFC #16001

Dear All,

I write to you, as signatories and cc's of the attached EPA denial of HSIA's Request for Correction of the TSCA Work Plan TCE assessment, to request that we be given until March 1, 2017 to submit our Request for Reconsideration (RFR) of same. The EPA denial, although dated November 4, 2016, was not received in any form by HSIA until November 30, 2016, when it came in the mail (see below). The requested date is 90 days after receipt.

I would greatly appreciate hearing from one of you whether the suggested RFR date is acceptable.



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